Reference number(s)
3470-A

SPECIALTY GUIDELINE MANAGEMENT

ENHERTU (fam-trastuzumab deruxtecan-nxki)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Breast Cancer
Enhertu is indicated for the treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive, unresectable or metastatic breast cancer who have previously received treatment with two or more prior anti-HER2 based regimens in the metastatic setting.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of human epidermal growth factor receptor 2 (HER2) status is necessary to initiate the prior authorization review.

III. CRITERIA FOR INITIAL APPROVAL

Breast cancer
Authorization of 12 months may be granted for treatment of HER2-positive metastatic or unresectable breast cancer in members who have received two or more prior anti-HER2 based regimens in the metastatic setting.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for breast cancer when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Enhertu [package insert]. Basking Ridge, NJ: Daiichi Sankyo Inc.; December 2019.